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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,697	09/15/2003	William J. Boyle	ACS 65470 (2309D)	9777

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EXAMINER

WEBB, SARAH K

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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11/29/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/662,697	Applicant(s) BOYLE ET AL.	
	Examiner SARAH WEBB	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 35-74 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 35-74 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/11/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 8/15/2011 has been entered.

Specification

2. The disclosure is objected to because of the following informalities: the first line of the specification should be amended to reflect that Application No. 09/845,758 is now Patent No. 6,645,223. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 35-74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed specification appears to lack adequate support for the requirement that the inner catheter extends a distance of at least 3 centimeters past the distal end of the recovery sheath in the delivery position, as now recited in independent claims 35, 45, 54, and 68. The specification merely discloses in paragraph 37 that the recovery sheath can be 10-15 cm shorter than the inner catheter and that the inner catheter extends beyond the sheath in the delivery position. Nowhere is a length of the distal end of the inner catheter extending past the sheath in the delivery position defined. Therefore, the specification as originally filed does not appear to support the language specifying the distance of *at least 3 centimeters* between the distal ends of the catheters in the delivery position.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 35-53 and 63-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "sufficient" in the requirement in independent claims 35, 45, and 68 is a relative term which renders the claims indefinite. The term "sufficient column strength" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Although the

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specification discusses materials that have sufficient strength to hold a compressed strut assembly (paragraph 44), the specification does not disclose material properties/compositions that meet that provide a sheath with "sufficient column strength" for performing the function of collapsing an expanded filter within the body. Dependent claims 36-44, 46-53, 63-67, and 69-74 are indefinite for the same reason, since they include all the limitations of the independent claims.

5. Claim 56 recites the limitation "may be up to approximately" in line 2, which renders the claim indefinite because the scope of the claimed range cannot be determined.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 35-40, 42-50, and 54-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,171,327 (Daniel et al.) in view of US Patent No. 6,887,256 (Gilson et al.).

Regarding claims 35, 45, 54, and 68: Daniel illustrates a catheter system in Figures 20-23 that is designed for recovery of an embolic filter (21) that is disposed on a guide wire (26). The system comprises an inner catheter (172 in Figure 20 or 372 in Figure 23) that moves along the guidewire (26) and has a distal portion made of flexible

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tubing (column 8, lines 61-67). A control handle (710) is connected to the proximal end of the inner catheter (372) (see Figure 24-26). The system further comprises a recovery sheath (151) with a control handle (702) at its proximal end (Figures 24-26). The inner catheter (172) is loaded inside the recovery sheath (151). The inner and outer catheters are capable of being positioned relative to another so that the distal end (180) of the inner catheter (172) extends distally beyond the recovery sheath (151), as shown in Figure 20. In this delivery position, both catheters are advanced along the guidewire (260) in proximity to a filter (21). As evidenced by the fact that the recovery sheath (151) is capable of deforming the tabs (182) on the distal end (180) of the inner catheter when pushed distally to retrieve the filter (Figure 21), the sheath (151) is considered to have “sufficient column strength” to collapse the filter (shown in Figure 19). Regarding claims 54 and 55, Daniel discloses steps of using the device in column 10 that include advancing the inner catheter and recovery sheath over a guide wire, locking the inner catheter to the guide wire, advancing the recovery sheath over the filter to collapse it, and removing the entire system from the patient's body.

The requirement “*the longitudinal length of the distal portion of the inner catheter which extends distally out of the distal end of the recovery sheath is at least 3 centimeters*” is a recitation related to the claimed “delivery position.” The requirement is a recitation of a relative position of two moveable components. The prior art is not required to specifically show the claimed delivery position of the components, and the position shown in Figure 20 of Daniel is not necessarily the claimed delivery position. As long as the prior art is *capable of* being manipulated to a position where the inner

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catheter extends 3 centimeters distally from the recovery sheath, it meets this claim requirement.

In this case, the inner and outer catheters are moveable relative to one another so that the inner catheter extends distally of the outer sheath, but Daniel is silent with respect to the lengths of the inner and outer catheters and the distance of relative movement between them. Daniel does teach that the catheters can have a range of sizes (column 3, lines 62-65; column 7, lines 63-67) and the length of the catheter can be adjusted to so that it is appropriate for a specific use (column 4, lines 1-6). Gilson discloses a similar filter retrieval assembly in Figures 42-47 that comprises an inner catheter (121) and recovery sheath (3) advanced over a guidewire (99) carrying a filter (40). Gilson teaches that the inner catheter (121) should be configured to extend distally beyond the distal end of the recovery sheath (3) a length sufficient to prevent snagging of the sheath on a stent (113) that has been delivered to the treatment site and minimize vessel trauma (column 20, lines 38-48). In light of Gilson's teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Daniel assembly so that the inner catheter has the capability of extending at least 3 centimeters beyond the distal end of the recovery sheath in order to prevent snagging on a deployed stent and to minimize vessel trauma. This modification merely involves a change in length of a component or amount of relative movement between components, which is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Regarding claims 36, 46, 56, 57, and 69: the language "may be up to", "may be up to approximately", and "may extend up to" is significantly broad to include any length less than the stated dimension. This range is significantly broad enough to encompass lengths of the recovery sheath and inner catheter that are substantially equal, so that the difference between their lengths is zero. Therefore, the Daniel device meets this broad requirement.

Regarding claims 37, 38, 47, 48, 64, 66: Daniel fails to disclose whether the inner catheter or outer sheath has greater column strength or flexibility than the other. Daniel does teach that the catheters can be made of any appropriate material known to those of ordinary skill in the art in order to provide the device with the desired degrees of rigidity and flexibility to be advanced through tortuous paths (column 4, lines 7-12; column 8, lines 10-13). Applicant has not disclosed that the greater column strength or flexibility of one component or the other provides an advantage or solves a stated problem. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to form the inner catheter to have greater column strength than the recovery sheath or to form the recovery sheath to have greater column strength than the inner catheter, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the combination of material properties

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disclosed by Daniel, because the Daniel device achieves the same objective of tracking a recovery sheath over an inner catheter to retrieve a filter.

Regarding claims 39, 40, 44, 49, 50, 58-62, 70, 71: Inner catheter (372) can be locked onto the guide wire (26) by way of a threaded connection between the handle (710) and a locking mechanism that includes a guide wire clamp (720) and a collet (718). The recovery sheath control handle (702) is locked with the inner catheter control handle (710) by a stop (708) that prevents the handles (702,710) from becoming separated but allows the handles to slide relative to one another.

7. Claims 41-43, 51-53, 72, 73, and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniel in view of Gilson, as applied above, and further in view of US Patent No. 5,201,757 to Heyn et al.

The relative position of the handles of the modified Daniel assembly is switched so that control handle of the recovery sheath is coaxially disposed within the lumen of the control handle of the inner catheter. Heyn discloses a device with control handles for sheaths that move relative to one another. Heyn teaches that the control handle (60) for the inner catheter (44) can be disposed within the control handle (56) of the outer sheath (20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to simply rearrange the control handles of the modified Daniel device so that the control handle of the inner catheter is disposed within the lumen of the recovery sheath handle, as Heyn teaches that this is an alternate way to configure control handles of relatively moving sheaths.

Response to Arguments

8. Applicant's arguments filed 8/15/2011 have been fully considered but they are not persuasive. Applicant argues that Daniel only includes a small portion (180) of the inner catheter that extends distally to the recovery sheath (150). As explained above, the position shown in Figure 20 is not necessarily the claimed "delivery position", the components are moveable relative to one another to a variety of positions. Daniel also does not disclose lengths of components, so it is unknown whether distal portion (180) extends 3 cm past the sheath in Figure 20 or not. While the Examiner agrees that the claims now further define the "distal portion" of the inner catheter that extends past the recovery sheath in the delivery position, this limitation is based on a particular position of two relatively moveable components and is therefore considered as functional language not given full patentable weight. Applicant asserts that Figure 20 illustrates the inner catheter in its furthest distally extending position, but this is simply not explicitly stated by Daniel. Gilson provides motivation for configuring an inner catheter so that it is capable of extending distally beyond the outer sheath in the delivery position by teaching that this avoids snagging of the outer sheath on a deployed stent and reduces vessel trauma. Since a mere change in length of one of the components of Daniel or a change in the distance of the relative movement of the components of Daniel would achieve the claimed distance between the distal ends of the components in a particular position and Gilson discloses that this configuration is known in the art to be beneficial, this requirement is considered to be an obvious modification of Daniel and within an ordinary level of skill in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah Webb whose telephone number is (571)272-5749. The examiner can normally be reached on Monday through Friday from 9:00 AM-5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Tom Hughes, at (571) 272-4357***. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to

TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SARAH WEBB/
Examiner, Art Unit 3731